DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 21,2014

SGS International Ltd.
C/O Ms. Daniela Levy
Regulatory Consultant
Sterling Medical Registration
22817 Ventura Blvd. #161
Woodland Hills, CA 91364

Re: K133362
Trade/Device Name: SGS Dental Implant Systems
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: October 21, 2014
Received: October 24, 2014

Dear Ms. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA

Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 - **Indication for Use Statement**

510(k) Number (if known): K133362

Device Name:

SGS® Dental Implants System

Indications for Use (Describe)

SGS® Dental Implants System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. SGS® Dental Implants System may be immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Two Stage Implants: P1, P7, P7N.

One Stage: P7S, P9S.

One Stage & One-Piece 3.0 mm diameter implants: P7S, P9S are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants.

One stage & One-Piece 2.4 mm diameter implants for temporary use or long term use: P9S permit immediate splint stability and long term fixation of new or existing crown, bridge and prosthesis.

PEEK Temporary Abutments are for 30 days.

Type of Use (Select one or both, as applicable)

!81Prescription Use (Part 21 CFR 801 Subpart D) **O** Over-The-Counter Use (21 CFR 801 Subpart

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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SECTION 5 - 510(k) Summary (21 CFR 807.92)

510(k) Number K133362

1	Submission Owner	SGS International Ltd. Michaeli Shabtai – CEO Karolyi Istvan Street 1-3. Budapest, Hungary H 1047, Hungary Telephone Number +36-309611579 Facsimile (Fax) Number +36-309611579
2	Official Correspondent Contact Person	Sterling Medical Registration Daniela Levy - Regulatory Consultant 22817 Ventura blvd. #161 Woodland Hills, CA 91364 Phone: 1-213-787-3026 Fax: 1-213-447-5297 Email: Daniela@sterlingmedicalregistration.com
3	Submission Date	October 23, 2013
4	Device Trade Name	SGS® Dental Implants System
5	Regulation Description	Root-form Endosseous Dental Implants & Abutments
6	Classification	Device Name : Implant, endosseous, root-form Product Code : DZE Regulation No : 872.3640 Class : II Panel : Dental Subsequent Product Code: Name : Abutment, implant, dental, endosseous Product Code : NHA Regulation No : 872.3630

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Class : II

Panel : Dental

7 Reason for the Premarket Notification Submission : New Device

8 Identification of Legally Marketed Predicate Devices :

SGS® Dental Implants System is substantially equivalent to A.B.Dental Devices ltd K051719, K112440, K132125; M.I.S, K092555, K040807,K103089; Alpha Bio Tec K063364; Nobel Active Multi Unit Abutment K072570; DIO Biotite-H Implant Systems K073070; in terms of intended use, indication for use, technological characteristics, performance and user interface.

The predicate devices are a Class II medical device.

9 Device Description: :

SGS® Dental Implants System consists of one and two stage endosseous form dental implants, internal hexagonal and one piece implants system;

P1 - Screw Type Groovy Implant- Diameter 3.2, 3.75,4.2, 5, 6 Length 8, 10,11.5,13,16

P7 - Conical Groovy Implant - Diameter 3.2, 3.75,4.2, 4.5, 5, 6 Length 8, 10,11.5,13,16 (13,16 not for 3.2 dmm).

P7N - Narrow Conical Implant - Diameter 3, 3.2 Length 10, 11.5, 13, 16

P7S - Integral Groovy Implant - Diameter 3, 3.2, 3.75, 4.2, 5, 6 Length, 10, 11.5, 13, 16

P9S - Thin Integral Implant - Diameter 2.4, 3, 3.2 Length 10, 11.5, 13, 16

Abutments System is compromised of Healing Abutments, Overdenture ball attachments, Straight Titanium Abutments, Angulated Titanium Abutments 15,25, Anatomic Straight Titanium Abutments, Anatomic Angular Titanium Abutments, Anatomic Straight Zirconium Abutments, Anatomic Straight PEEK Abutments, Temporary Abutments, Screw Type Abutments, Screw Type Angular Abutments and Attachments for Overdenture; impression copy system & surgical instruments are also provided.

10 Intended use / Indication for Use: :

SGS® Dental Implants System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. SGS® Dental Implants System may be immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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Two Stage Implants: P1, P7, P7N.

One Stage: P7S, P9S.

One Stage & One-Piece 3.0 mm diameter implants: P7S, P9S are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants.

One stage & One-Piece 2.4 mm diameter implants for temporary use or long term use: P9S permit immediate splint stability and long term fixation of new or existing crown, bridge and prosthesis.

PEEK Temporary Abutments are not to exceed 30 days.

11 Performance Standards or Special Controls :

- ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.
- ISO 5832-3:1996 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.
- ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants.
- FDA guidance document: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff.

12 Substantial Equivalence

Characteristic	**P1 Screw Type Groovy Implant**	**Predicate Implant**
510(k) number	TBD	K112440
Manufacturer	SGS International Ltd.	AB Dental Ltd.
Product Name	P1 Screw Type Groovy Implant	I2 Screw Type
Placement Method	Dual step surgery. Later exposure required	The same
Length	8, 10, 11.5, 13, 16	8, 10, 11.5, 13, 16, 18, 20
Available diameters	3.2, 3.75, 4.2, 5, 6	3.25, 3.75, 4.2, 4.5, 5, 6
Integrated abutment	No	No
Material	Ti 6Al-4V ELI	same

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External surface	Calcium Phosphate	Sandblasted and acid etched surface (HA)
Self tapping	Yes	Yes
Characteristic	**P7 Conical Groovy Implant**	**Predicate Implant**
510(k) number	TBD	K051719, K112440
Manufacturer	SGS International Ltd.	AB Dental Ltd.
Product Name	P7 Conical Groovy Implant	I5 Conical
Placement Method	Dual step surgery. Later exposure required	The same
Length	8, 10, 11.5, 13, 16 (13,16 not for 3.2 dmm)	8, 10, 11.5, 13, 16
Available diameters	3.2, 3.75, 4.2, 4.5, 5, 6	3, 3.2, 3.75, 4.2, 4.5, 5, 6
Integrated abutment	No	No
Material	Ti 6Al-4V ELI	The same
External surface	Calcium Phosphate	Sandblasted and acid etched surface (HA)
Self tapping	Yes	Yes
Characteristic	**P7N Narrow Conical Implant**	**Predicate Implant**
510(k) number	TBD	K132125
Manufacturer	SGS International Ltd.	AB Dental Ltd.
Product Name	P7N Narrow Conical Implant	I6B Narrow Implant
Placement Method	Dual step surgery. Later exposure required	same
Indication for use	Used in soft bone and designed to enable the change of direction during implantation	same
Length	10, 11.5, 13, 16	10, 11.5, 13, 16
Available diameters	3, 3.2	3, 3.2
Integrated abutment	No	No
Material	Ti 6Al-4V ELI	The same
External surface	Calcium Phosphate	Sandblasted and acid etched surface (HA)
Self tapping	Yes	Yes
Characteristic	**P7S Integral Groovy Implant**	**Predicate Implant**
510(k) number	TBD	K051719, K112440
Manufacturer	SGS International Ltd.	AB Dental Ltd.

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Product Name	P7S Conical Groovy Implant	I7 Integral
Placement Method	Single step. No exposure required	same
Length	10, 11.5, 13, 16	10, 11.5, 13, 16
Available diameters	3, 3.2, 3.75, 4.2, 5, 6	3, 3.2, 3.75, 4.2, 5, 6
Integrated abutment	No	No
Material	Ti 6Al-4V ELI	same
External surface	Calcium Phosphate	Sandblasted and acid etched surface (HA)
Self tapping	Yes	yes
Characteristic	**P9S One-piece Esthetic Implant**	**Predicate Implant**
510(k) number	TBD	K132125
Manufacturer	SGS International Ltd.	AB Dental Ltd.
Product Name	P9S Integral Groovy Implant	I6 Narrow Integral Implant
Placement Method	Single step. No exposure required	same
Length	2.4, 3, 3.2	2.4, 3, 3.2
Available diameters	10, 11.5, 13, 16	10, 11.5, 13, 16
Integrated abutment	Yes	Yes
Material	Ti 6Al-4V ELI	same
External surface	Calcium Phosphate	Sandblasted and acid etched surface (HA)
Self tapping	Yes	yes

SGS Dental Implants uses BONIT surface treatment - Calcium Phosphate(CaHPO 4 2H20) which is substantially equivalent to DIO Biotite-H Implant Systems K073070.

Summary of Equivalence:

SGS® Dental Implants System shares similarity to its predicate devices in terms of intended use, indication for use, technological characteristics, performance and user interface.

As demonstrated by the substantial equivalent table, the differences raise no new issues of safety or effectiveness, since SGS® Dental Abutments System shares similarity or very identical to its predicate devices.

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Non Clinical Testing

Mechanical Testing - SGS® has conducted Fatigue – Static & Cycling tests which comply with ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants. The test results have demonstrated the high resistance and high ability with the use of SGS® Dental Implant System. Therefore, SGS® Dental Implants System raises no new issues of safety or effectiveness than the predicate devices.

Safety & Effectiveness testing

Safety & Effectiveness testing such as Sterilization Validation, Cleaning validation, Packaging Validation, Shelf Life were used to demonstrate the safety & effectiveness.

Risk Assessment was conducted and has demonstrated no new safety and/or effectiveness issues than the predicate devices.

Conclusion:

As verified by clinical and non clinical data, bench testing, mechanical testing, risk assessment and substantial equivalence, SGS® Dental Implant System shares similarity with its predicated devices by term of intended use, raw material and technical design. The fundamental scientific technology of the device is very similar to the referenced predicate devices, thus SGS® Dental Implant System is considered to be substantially equivalent to its predicate devices and raises no new safety and/or effectiveness issues than the predicate devices.